Breast Cancer Test Receives Health Canada Approval

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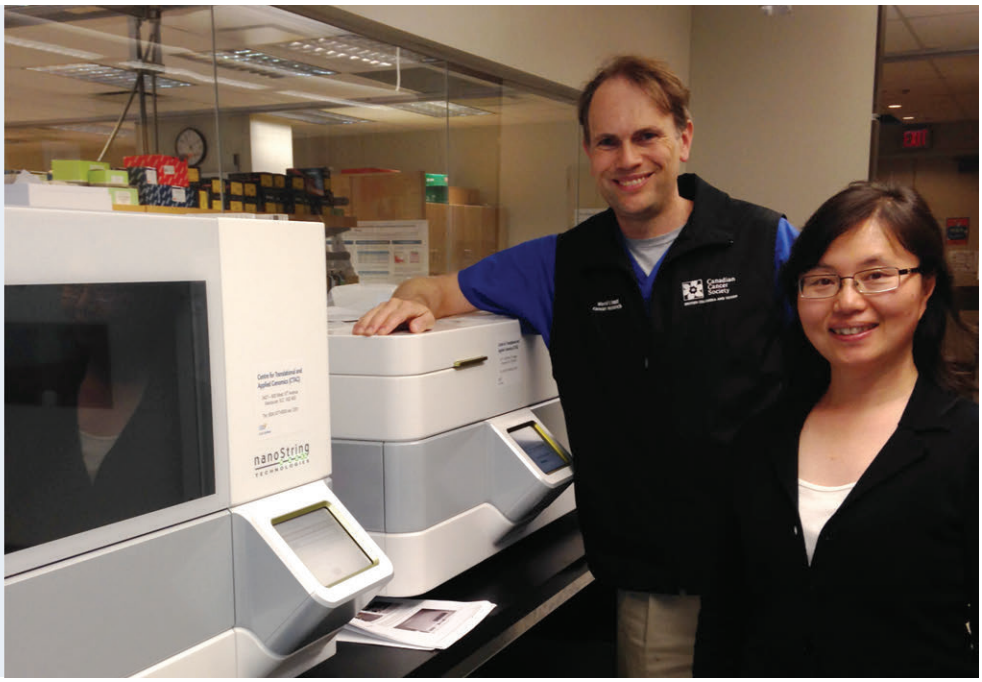
When Dr. Torsten Nielsen was a resident in the UBC Anatomical Pathology program, he was given the opportunity to go abroad on research electives, spending time in England and at Stanford University. Fourteen years later, research he started as a resident, and which continued after his recruitment as a faculty member in Pathology and Laboratory Medicine, has led to the development of the PAM50 breast cancer molecular subtyping test. NIH-funded work done at the Genetic Pathology Evaluation Centre (at VGH) and the Centre for Translational and Applied Genomics (at BCCA), in collaboration with three US institutions, led to the identification of a panel of fifty key breast cancer genes for which mRNA levels could be reliably measured from standard pathology blocks. In April of 2014, the commercialized clinical version of the PAM50 test, licensed to NanoString Technologies under the brand name Prosigna (www.prosigna.com), was approved as a clinical diagnostic test by Health Canada. Other regulatory approvals include 510(k) clearance by the US Food & Drug Administration in the USA and receipt of a CE mark in the European Union. The Prosigna test identifies the intrinsic subtype of breast cancer – something not easily identified by morphology – assigns a risk of relapse score, and is capable of identifying a large fraction of women with >96% 10 year distant relapse-free survival. Such women do not need adjuvant chemotherapy, saving them unnecessary costs and side effects. Unlike other tests which require samples to be shipped out of country, Prosigna was designed and is approved to be run on-site in hospital diagnostic labs, cutting costs, shortening turnaround time and facilitating direct involvement of pathologists in test implementation and interpretation.



Professor Torsten Nielsen, co-inventor of the PAM50 assay, and his senior research associate Suzanne Liu, project director for the successful Health Canada and FDA registry study, standing beside a NanoString nCounter machine used to measure RNA expression in breast cancer tumor samples